



Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

Recruitment Process

Recruitment Process

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1.0 Purpose

To aid in assuring knowledge and compliance of all persons involved in any aspect of human subject research by documenting the requirements for subject recruitment methods and compensation of participants.

2.0 Scope

The SOP applies to all human subject research falling under the purview of the University of Missouri Institutional Review Board.

3.0 Policy/Procedure

45 CFR 46.111(a)(3) requires selection of subjects to be equitable. In making this assessment, the IRB will take into account the purposes of the research and the setting in which the research will be conducted and will be particularly cognizant of research recruiting vulnerable populations.

The recruitment process and materials are reviewed by the IRB to assure that potential subjects are not unduly coerced or influenced, and the recruitment strategies respect an individual's reasonable expectation for privacy. The inclusion and exclusion criteria are reviewed by appropriate study personnel to determine the subject population is appropriate for the study

SOP – Recruitment Process
Page 2 of 7

objectives, and the methods of recruitment are acceptable. Study personnel authorized to obtain consent should be able to determine eligibility unless the approved study protocol or IRB application states otherwise.

Recruitment Materials Including Advertisements:

Recruitment materials include information that may be shared through a variety of sources which may include electronic as well as hard copy media. Recruitment advertisements can be included as part of the recruitment process and information may be shared at different time points but prior to subject enrollment. One advertisement may not be inclusive of all required elements, and the investigator will ensure the required information is shared in some manner, whether written or verbal, prior to subject enrollment. Recruitment materials should be limited to information the prospective subjects need to determine their eligibility and interest.

The MU IRB requires the following be included in advertisements:

- The location or research facility and the person or office to contact for further information
- A statement the study involves research, and the condition under study or the purpose of the research
- In summary form, the criteria that will be used to determine eligibility for the study

The following may be required if determined it would be helpful or necessary to communicate up front, or an investigator may just choose to include these:

- A brief list of participation benefits, if any
- The name of the investigator or research facility
- The time or other commitment required of the subjects
- Additional study-specific information

1. The recruitment materials cannot:

- State or imply a certainty of favorable outcome or other benefits beyond what was outlined in the consent document and the protocol
- Make claims, either explicitly or implicitly, that the drug, biologic or device was safe or effective for the purposes under investigation
- Make claims, either explicitly or implicitly, that the test article was known to be equivalent or superior to any other drug, biologic or device
- Use terms, such as “new treatment,” “new medication” or “new drug” without explaining that the test article was investigational
- Promise “free medical treatment,” when the intent was only to say participants will not be charged for taking part in the investigation
- Include exculpatory language

SOP – Recruitment Process
Page 3 of 7

- Emphasize the payment or the amount to be paid, by such means as larger or bold type

All final recruitment advertisements must be submitted for IRB review and approval, including but not limited to, newspaper, television, radio, scripts, emails, social media, letters, and flyers.

Depending on the location of recruitment, if permission is required from the site(s), the investigator must maintain the records of permission. Unless requested by the IRB, permission does not need to be uploaded to the study for IRB record keeping.

Recruitment Materials Utilizing Social Media and Recruitment Panels

1. Social Media:

Investigators need to carefully consider whether use of social media is an appropriate and effective means for reaching their target study population, and design recruitment methods to adhere to ethical principles outlined in the Belmont Report. Some additional considerations for using social media for recruitment efforts:

- A. The social media platform(s) to be used must be identified and justification for the appropriateness of choosing the platform.
- B. The timing and frequency of advertising must be described.
- C. How investigators will engage with users must be described and address any privacy concerns associated with engaging with others.
- D. How investigators will manage recruitment content and responses received. This must be described because sometimes the control of the content is not handled by the investigator directly.
- E. How investigators will address privacy and confidentiality of discussions and questions received during the recruitment process must be described.
- F. Policies, rules, restrictions, and norms of the site must be known to the investigator. If permission is required by a site administrator prior to posting recruitment and/or engaging with users of the site, permission must be obtained and documented by the investigator.
- G. Utilize MU email contact information in advertisements and avoid including investigator's personal contact information when possible.
- H. Investigators must describe the process for directing potential subjects to the research study/location. A description of any eligibility screening processes must be disclosed.
- I. Submit to the IRB all final versions of the recruitment advertisements/scripts (these should be PDF or Word or image files uploaded to eCompliance and not a link to a website/URL). Social media recruitment materials are reviewed and approved by the IRB in the same manner as all research advertisements and must follow the same standards outlined in this policy.

2. Recruitment Panels:

An online recruitment panel, such as Amazon Mechanical Turk and Qualtrics, allows you to send your survey to a targeted population of respondents. Investigators can target respondents based on demographic information such as race, location, age, gender, or ethnicity. MU HRPP/IRB supports the use of recruitment panels to aid with subject recruitment that are supported by MU IT, but there are some considerations that require attention:

- A. Advertisement: MU IRB must approve final versions of advertisements. It is common for research panel advertisements to limit the amount of information that initially can be shared. If the language shared with prospective subjects is study specific, it must be reviewed and approved by the IRB.
- B. Screeners: Potential subjects should be told if there is a screener in order to qualify. It would be important for investigators to make clear if subjects are being paid for the time it takes to complete the screener.
- C. Compensation: The amount of compensation is typically set by the amount of time required by the study. The amount of compensation is set between the potential subject/employee and the company/recruitment panel.
 - i. If the exact amount is known, the amount needs to be disclosed.
 - ii. If the exact amount is unknown to the investigators or is different for each potential subject, the following sample language is acceptable to include: “After responding to the survey, you will receive information about the payment you are eligible for based on your agreement with XX/company name. Compensation will range in value from \$X to \$X. If the compensation you received does not align with your expectations for this study, please contact the PI at XXX.” The suggested language may be edited as necessary, but the language proposed must receive IRB approval.
 - iii. If the investigator receives multiple complaints regarding compensation, the MU IRB may discontinue the use of the panel for research purposes by MU investigators. This decision will be made on a case-by-case basis.
- D. Confidentiality: The level of de-identification would depend on the company used and how the study is designed. It is important for investigators to understand whether data can be collected anonymously or whether certain identifiers are linked to the dataset. It may be possible for the investigator to obtain only de-identified completed information/data, but the company may be able to retain identifiers linked to the information/data collected for the study. Confidentiality must be disclosed in the consent and describe levels of security to maintain confidentiality.
- E. Incomplete Disclosure & Deception: Investigators must provide a debriefing opportunity. The debriefing process and document must be reviewed and

approved by the MU IRB. The debriefing form would require participants to answer a final question giving researchers permission to use their data.

Identifying Subjects through their Medical Record

If an investigator is utilizing the medical record to identify and contact subjects in a study, the plan must meet at least one of the following requirements:

1. One or more investigators on the IRB submission have a treating/provider relationship with the patients as potential subjects and will be providing oversight regarding utilization of any PHI for the research.
2. There is no treating/provider relationship. The research team members will work directly with providers who have a treating (patient-provider) relationship who will be providing oversight regarding utilization of any PHI, before contacting patients as potential subjects. This option requires consultation with a SOM department that provides clinical care or with the SOM CTSO. The MU HRPP/IRB will consider past noncompliance for investigators listed on the study before allowing this option.
 - In this instance, the recruitment materials must state how the investigators obtained potential participant information and their relationship with the health system, that the investigators consulted with potential participant providers, and how the investigators will maintain confidentiality of protected health information.
3. There is no treating/provider relationship, and there is no plan to work directly with a provider with a treating/provider relationship prior to initial contact with patients as potential subjects. The investigators must use the MU IRB templates for cold contacting. The details regarding the process to initially contact potential participants will be reviewed by the MU IRB and be approved on a case-by-case basis. This option requires consultation with a SOM department that provides clinical care or with the SOM CTSO. The MU HRPP/IRB will consider past noncompliance for investigators listed on the study before allowing this option. The following must also be in place when planning to cold contact:
 - At least one member on the research team is a full-time, non-trainee employee of MU Health. This excludes residents, fellows, and students.
 - The MU Health employee(s) must be listed as PI or co-investigator.
 - The MU Health employee(s) accessing, using, or sharing PHI assumes responsibility to ensure the research members making initial contact with potential participants have adequate training and resources, and follows the IRB approved script for initial contact. The SOM department providing clinical care or the SOM CTSO will ensure adequate training and resources. Adequate documentation of support will be required.
 - The PI has a plan in place that has been approved by the SOM department or CTSO to address concerns or questions from potential participants regarding the pre-screening process and use of PHI.

HIPAA regulations apply to the screening process and access to protected health information. The IRB will review requests for HIPAA waivers or alterations when necessary.

Recruitment Assistance – Determining Engagement:

Institutions/organizations whose employees or agents only participate in the following ways are not engaged in the research and do not need to be added to the IRB application as key personnel:

1. inform prospective subjects about the availability of the research;
2. provide prospective subjects with information about the research (which may include a copy of the relevant informed consent document and other IRB approved materials) but do not obtain subjects' consent for the research or act as representatives of the investigators;
3. provide prospective subjects with information about contacting investigators for information or enrollment; and/or
4. seek or obtain the prospective subjects' permission for investigators to contact them.

An example of this would be a clinician who provides patients with literature about a research study at another institution, including a copy of the informed consent document, and obtains permission from the patient to provide the patient's name and telephone number to investigators.

See OHRP Engagement Guidance for more information:

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html>

Subject Compensation:

Although it is common, it is also not required for subjects to be compensated for reimbursement for time and/or expenses incurred as part of the research study. The IRB will determine on a case-by-case basis whether the amount of compensation is appropriate, and upon review, may request changes in the amount or method of compensation. The IRB will consider:

1. The amount of payment and the proposed method and timing of disbursement neither is coercive nor presents undue influence and is reflective of the degree of risk, inconvenience, or discomfort associated with participation.
2. Credit for payment accrues as the study progresses and not be contingent upon the participant completing the entire study.
3. Any amount paid as a bonus for completion is reasonable and not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn.

4. All information concerning payment, including the amount and schedule of payments, is set forth in the consent document.

Compensation for participation in a trial offered by a sponsor to include a coupon good for a discount on the purchase price of the product once it has been approved for marketing is prohibited.

Investigators must work directly with their department's fiscal office to ensure compliance with the MU Business Policy and Procedure for Research Participation Payments found here: https://bppm.missouri.edu/policy/research-participation-payments/?_ga=2.23105082.1689524572.1539115672-2052305340.1537195229

Finder's and Referral Fees, and Bonus Payments

Payment arrangements can potentially place participants at risk of coercion or undue influence or cause inequitable selection. Finder's fee or referral is a payment from the researcher or sponsor to a person who refers a prospective participant. Recruitment bonuses are payments from the sponsor to a researcher or organization based on the rate or timing of recruitment.

The IRB may allow finder's fees or referral fees on a case-by-case basis if appropriate justification is provided and the potential for coercion or undue influences is minimized.

The IRB will not allow bonus payments which are designed to accelerate recruitment that are tied to the rate or timing of enrollment.

References:

Combined Policy January 21, 2019:
Subject Compensation

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